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 le — Letter from the editor
 nl — News from the literature
 oa — Original article
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 pq — Pathology quiz
 s — Symposium

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continued

Schering

Gyne-Lotrimin®
brand of
clotrimazole

Vaginal Tablets Vaginal Cream 1%

Combined Brief Summary

INDICATIONS: GYNE-LOTTRIMIN Vaginal Tablets and Vaginal Cream are indicated for the local treatment of vulvovaginal candidiasis.

CONTRAINDICATIONS: GYNE-LOTTRIMIN Vaginal Tablets and Vaginal Cream are contraindicated in women who have shown hypersensitivity to any of the components of the preparation.

PRECAUTIONS: Laboratory Tests: If there is a lack of response to GYNE-LOTTRIMIN, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens before instituting another course of antimicrobial therapy.

Application of ¹⁴C-labeled clotrimazole has shown negligible absorption: (peak of 0.03 mcg/ml of serum 24 hours after insertion of a 100 mg. tablet; peak serum level of 0.01 mcg/ml 24 hours after insertion of vaginal cream containing 50 mg. of active drug) from both normal and inflamed human vaginal mucosa.

Usage in Pregnancy: While GYNE-LOTTRIMIN Vaginal Tablets and Cream have not been studied in the first trimester of pregnancy, use in the second and third trimesters has not been associated with ill effects. Follow-up reports now available on 71 neonates of 177 pregnant patients treated with GYNE-LOTTRIMIN Vaginal Tablets reveal no adverse effects or complications attributable to GYNE-LOTTRIMIN therapy.

ADVERSE REACTIONS: Eighteen (1.6%) of the 1116 patients treated with GYNE-LOTTRIMIN Vaginal Tablets in double-blind studies reported complaints during therapy that were possibly drug-related. Mild burning occurred in six patients while other complaints, such as skin rash, itching, vulvar irritation, lower abdominal cramps and bloating, slight cramping, slight urinary frequency, and burning or irritation in the sexual partner, occurred rarely.

Three (0.5%) of the 653 patients treated with GYNE-LOTTRIMIN Vaginal Cream reported complaints during therapy that were possibly drug-related. Vaginal burning occurred in one patient, erythema, irritation and burning in another; intercurrent cystitis was reported in the third. **DOSAGE AND ADMINISTRATION:** The recommended dose of GYNE-LOTTRIMIN Vaginal Tablets is one tablet a day for seven consecutive days. Recent studies indicate that an alternative regimen of two tablets a day for three consecutive days is similarly effective in non-pregnant patients; however, in pregnant patients the three-day treatment course did not prove to be effective and is therefore not recommended. They should receive the seven-day treatment. Using the applicator supplied, insert one or two tablets intravaginally preferably at bedtime.

In the event of treatment failure, other pathogens commonly responsible for vaginitis should be ruled out before instituting another course of antimicrobial therapy. There are no studies to show whether a second course of clotrimazole would be effective in patients who fail to respond to the initial course.

GYNE-LOTTRIMIN Vaginal Cream has been found to be effective when used from seven to fourteen days; studies have shown that patients treated for fourteen days had a significantly higher cure rate. The recommended dose is one applicatorful of cream (approximately 5 grams) intravaginally preferably at bedtime.

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Schering Corporation
Kenilworth, New Jersey 07033

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